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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT		ATTY. DOCKET NO.
09/087,136	05/28/98	HORVITZ	H	01997/202002

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EXAMINER	
WORRALL, T	
ART UNIT	**PAPER NUMBER**
1642	9

DATE MAILED: 06/25/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 5/28/98.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-33 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-33 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1998-404-496/40517

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-7, 10-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein LIN-37, SEQ ID NO:1, or SEQ ID NO:2, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

II. Claims 1, 4-7, 10-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein LIN-35, SEQ ID NO:3, or SEQ ID NO: 4, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

III. Claims 1, 3-7, 10-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein LIN-55, SEQ ID NO:7, or SEQ ID NO:8, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

IV. Claims 1, 4-7, 10-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein LIN-53, SEQ ID NO:5, or SEQ ID NO:6, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

V. Claims 1, 3-7, 10-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein LIN-52, SEQ ID NO:11, or SEQ ID NO:12, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

VI. Claims 1-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein LIN-54, or SEQ ID NO:13, 14, 15, or 16, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

VII. Claims 1, 4-7, 10-18, and 25, in part, to the extent that claims are drawn to nucleic acids encoding the protein E2F-1, vectors, host cells, and methods of making protein, classified in class 536, subclass 23.1+.

VIII. Claims 19 and 21, in part, drawn to the polypeptide LIN-37, or SEQ ID NO:1, and a therapeutic composition, classified in class 435, subclass 530+.

IX. Claims 19 and 21, in part, drawn to the polypeptide LIN-35 or SEQ ID NO:3, and a therapeutic composition, classified in class 435, subclass 530+.

X. Claims 19 and 21, in part, drawn to the polypeptide LIN-55, or SEQ ID NO:7, and a therapeutic composition, classified in class 435, subclass 530+.

XI. Claims 19 and 21, in part, drawn to the polypeptide LIN-53, or SEQ ID NO:5, and a therapeutic composition, classified in class 435, subclass 530+.

XII. Claims 19 and 21, in part, drawn to the polypeptide LIN-52, or SEQ ID NO:11, and a therapeutic composition, classified in class 435, subclass 530+.

XIII. Claims 19-21, in part, drawn to the polypeptide LIN-54, or SEQ ID NO:13, or 15, and a therapeutic composition, classified in class 435, subclass 530+.

XIV. Claims 19 and 21, in part, drawn to the protein E2F-1, and a therapeutic composition, classified in class 435, subclass 530+.

XV. Claim 26, drawn to an antibody specific to a SynMuv protein, classified in class 530, subclass 387.1+.

XVI. Claims 22-24, drawn to a method of modulating cell proliferation using a SynMuv polypeptide, classified in class 514, subclass 2+.

XVII. Claim 27, drawn to a method of identifying a compound modifying the expression of a SynMuv gene, classified in class 435, subclass 4+.

XVIII. Claims 28 and 30, in part drawn to a method of diagnosing a cell proliferation disease caused by a SynMuv mutation by detecting the mutated DNA, classified in class 536, subclass 24.3+.

XIX. Claims 28, and 30-32, in part drawn to a method of diagnosing a cell proliferation disease caused by a SynMuv mutation by assaying the amount of protein in a sample, classified in class 424, subclass 130.1+.

XX. Claim 29, 30, and 33, in part drawn to a method of diagnosing a cell proliferation disease caused by altered expression of a SynMuv gene by detecting increased expression of mRNA, classified in class 536, subclass 24.3+.

XXI. Claim 29 and 30-32, in part drawn to a method of diagnosing a cell proliferation disease caused by altered expression of a SynMuv gene by detecting the concentration of a protein, classified in class 424, subclass 138.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. The protein compositions of Groups (VIII-XIV) are related to the nucleic acids of Groups (I-VII) since the polynucleotides encode the protein compositions. Although they are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from non-recombinant cells. Further, the DNA may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature, and would require the consideration of different patentability issues.

4. The proteins of Groups (VIII-XIV) are related to the antibodies of Group XV by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two compositions, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used for other materially different processes in its own right, such as in a method of treatment, or in assays for the identification of agonists or antagonists for the protein. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

5. The nucleic acids of Groups (I-VII) and the antibodies of Group XV are different chemical compositions with different chemical properties and different methods of use. The examination of both groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

6. The nucleic acids of Groups I-VII are distinct inventions, since they encode proteins having different structures, different biochemical properties, and different functions. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

7. The proteins of Groups VIII-XIV are distinct inventions, since proteins have different structures, different biochemical properties, and different functions. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

8. The methods of Groups XVI, XVII, XVIII, XIX, XX, and XXI and VII differ in the method objectives, method steps and parameters, or in the regents used. The methods each have a different measurable endpoints and involves the consideration of different associated patentability issues. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

9. Inventions (I-VII) and (XVIII and XX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Inventions (I-VII) can also be used in gene therapy methods.

10. Inventions XV and (XIX and XXI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Invention XV can also be used to purify the proteins of Inventions (VIII-XIV).

11. Inventions (VIII-XIV) and (XVI and XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Inventions (VIII-XIV) can be used to make a polyclonal antibody.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

13. Any inquiry concerning the communication or earlier communications from the examiner should be directed to Timothy A. Worrall, Ph.D. whose telephone number is (703) 308-9348. The examiner can normally be reached on Monday through Friday from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014.

Communications via Internet-e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements under 35 U.S.C.122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997, at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Timothy A. Worrall, Ph.D.
June 21, 1999

JULIE BURKE
JULIE BURKE PRIMARY EXAMINER